REMARKS

1. Rejection of Claim 18 under 35 USC §112(2) and §101

This rejection should be withdrawn for the grounds noted at Section 1 of the Response dated August 10, 2005:

> Kindly withdraw this rejection, which is predicated on the basis that "the claim does not set forth any steps involved in the method/process...." However, note that claim 18 positively recites the step of "*applying topically to the affected area* an effective amount...." Further, while the rejection states that "'the use of' is not a statutory class of invention", we assert that the claim is an acceptable method/process claim reciting positive steps; see, e.g., MPEP 706.03(a), which notes that "[t]he term 'process' as defined in 35 USC 100, means process, art or method, *and includes a new use* of a known process, machine, manufacture, composition of matter, or material" (emphasis added). Here, since steps are recited, and a "use" is merely a method/process by another name, we submit that claim 18 meets all requirements of 35 USC §112(2).

Note that while the Final Office Action responds that the recitation of the "use of" a substance will not constitute a proper method claim (page 9 of the Final Office Action), the Office Action does not address why the "applying topically" step – a positively-recited step – does not make claim 18 an acceptable method claim. If the rejection is maintained, please address and respond to these arguments.[1]

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[1] See MPEP 707.07(f), Answer All Material Traversed ("Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it"); also see Examiner Notes for PTO form paragraphs 7.37 and 7.38 (as reproduced in MPEP 707.07), which require that all relevant arguments by the Applicant be addressed, as well as MPEP 706.07 under "Statement of Grounds" ("the final rejection . . . also should include a rebuttal of any arguments raised in the applicant's reply").

2. **Rejection of Claims 14-17 under 35 USC §103(a) in view of U.S. Patent 4,879,282 to *Saliba* and U.S. Patent 5,874,094 to *Costello***

Kindly reconsider these rejections, which are founded on an improper *per se* rule of obviousness at pages 4 and 5 of the Office Action, wherein it is stated:

> It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Saliba, Jr and Costello, to have used the method of Saliba, Jr to treat insect bites with a composition comprising a combination of sodium heparin and zinc oxide, since the combination of compounds that are used to treat the same diseases or condition are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

This is an improper use of a *per se* rule of obviousness, i.e., relying on a holding in a prior case based on different facts to the current case. This approach is incorrect because it fails to make the fact-intensive inquiry mandated by §103, and it does not show where the prior art would truly motivate or suggest one of ordinary skill in the art to make the asserted modification or combination. The Court of Appeals for the Federal Circuit has explicitly forbidden the use of *per se* rules in *In re Ochiai*, 37 USPQ2d 1127 (Fed. Cir. 1995):

> The use of per se rules, while undoubtedly less laborious than a searching comparison of the claimed invention -- including all its limitations -- with the teachings of the prior art, flouts section 103 and the fundamental case law applying it. Per se rules that eliminate the need for fact-specific analysis of claims and prior art may be administratively convenient for PTO examiners and the Board. Indeed, they have been sanctioned by the Board as well. But reliance on per se rules of obviousness is legally incorrect and must cease. Any such administrative convenience is simply inconsistent with section 103, which, according to Graham and its progeny, entitles an applicant to issuance of an otherwise proper patent unless the PTO establishes that the invention as claimed in the application is obvious over cited prior art, based on the specific comparison of that prior art with claim limitations. We once again hold today that our precedents do not establish any per se rules of obviousness, just as those precedents themselves expressly declined to create such rules. Any conflicts as may be perceived to exist derive from an impermissible effort to extract per se rules from decisions that disavow precisely such extraction.

Id. at 1133. See also *Litton Systems Inc. v. Honeywell Inc.*, 39 USPQ2d 1321, 1325 (Fed. Cir. 1996) ("As we expressly recognized in *Ochiai*, the obviousness inquiry is highly fact-specific and not susceptible to *per se* rules. The Supreme Court has underscored the fact intensive nature of the test for obviousness.").

Further, we respectfully submit that much of the reasoning underlying the rejections is erroneous in that it seems founded on the proposition that one *could* combine *Saliba* and *Costello* to attain the claimed compositions/methods rather than that the prior art suggests that one *should* modify the references to attain the claimed matter, setting forth statements such as:

- "this does not mean that concentrations outside this range will not be efficacious or effective although they may not be **most** efficacious" (page 7, emphasis in original);
- "this does not imply that the carrier has to be at an acidic pH to be efficacious or effective, but only to be **most** efficacious" (page 7, emphasis in original);
- "this does not mean that concentrations outside this range will not be efficacious or effective although they may not be **most** efficacious" (page 8, emphasis in original);
- "However, Saliba does not plainly suggest or vaguely suggest that one *cannot* add materials such as zinc oxide to heparin when used topically (as claimed). Firstly, Saliba does not suggest that zinc oxide is a carrier nor that zinc oxide or other compounds *cannot* be combined or added to heparin. Furthermore, Saliba does not suggest that compounds with pH's that are not acidic *cannot* be combined with heparin." (page 8, emphasis added).

However, these are not proper tests for obviousness. The obviousness inquiry is not properly addressed by asking whether an invention is *unobvious* only if the prior art references show or suggest that the claimed combination is *not* feasible or beneficial. Rather, the obviousness inquiry requires that one determine if the prior art references suggest that one *should* combine or modify features of a prior composition/method to arrive at the claimed composition/method. Further, the

references must *clearly and affirmatively* suggest the claimed invention.[2] As explained below, while *Saliba* and *Costello* do describe use of ingredients used in the claimed composition, we believe that the references, when considered fully, fairly, and objectively, cannot be said to fairly suggest the claimed matter. Please give balanced and careful consideration to the following.

Initially, reviewing the teachings of the cited references, *Saliba* expresses that heparin is useful for treating a huge range of conditions, including ailments as diverse as poisonings, "space-travel sickness,"electrical dysrhythmias of the nervous system, and stomach ulcers (see the Abstract and column 2 line 58 onward), as well as insect bites (see the foregoing, as well as column 7 lines 25-35) – and these ailments can be treated with either topical or injected heparin (see column 6 line 66-column 7 line 11). In essence, *Saliba* contends that heparin is effective when administered in almost any manner, to almost any ailment. *Saliba* also notes that when heparin is to be applied topically, it should be applied at concentrations of 1,500 IU - 5,000 IU per ml (see column 6 line 66 - column 7 line 35), and it should be accompanied by an acidic carrier (preferably with a pH of about 5.5); see column 7 lines 11-16.

Costello then discusses a topical cream using aloe vera as its key active ingredient, along with vitamin E and zinc oxide (see Abstract; column 3 lines 13-23). The cream contains 3-10 g of aloe vera, 200-900 IU (0.19-9.25 g) of vitamin E, and 0.4-1.5 g zinc oxide per ounce (an ounce being 28.47 g); see column 4 lines 29-36. This equates to a cream containing 10-15% aloe vera, 0.67-32% vitamin E, and 1.4-5.2% zinc oxide (by weight).

When the presently claimed invention is placed out of mind, and the cited references are objectively considered for all they suggest, it cannot fairly be said that one of ordinary skill would be led to combine them to obtain the claimed invention. Initially, even if one regarded *Saliba*'s

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[2]See, e.g., *Winner International Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1586 (Fed. Cir. 2000) (citations and footnotes omitted):

> When an obviousness determination is based on multiple prior art references, there must be a showing of some "teaching, suggestion, or reason" to combine the references. .... Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the **[1587]** showing of combinability, in whatever form, must nevertheless be 'clear and particular.'"

assertion of heparin-based insect bite treatment as credible, *Saliba* suggests use of heparin in a far greater amount than the amount claimed: 1,500-5,000 IU per milliliter, as compared to the 100-300 USP (IU) per gram claimed. The Examiner notes that the claimed composition and *Saliba* have different units (*Saliba* using 1,500-5,000 IU/ml and the claimed composition using 300 IU/g), and thus the two measures are not fully comparable, but consider that most aqueous substances have close equivalence between milliliter volume and gram mass (water having a volume of 1 ml per gram). Thus, even if it is assumed that the claimed range would be closer to the *Saliba* range if expressed in the same units, the ranges are still vastly different, with *Saliba* suggesting the use of *five to fifty times* the amount of heparin used in the claimed composition.

Further, *Saliba* does plainly suggest against the use of materials such as zinc oxide, which are fundamentally basic to neutral in pH,[3] with heparin, at least when used topically (as claimed); for example:

> The uses are realized by applying the [heparin] compounds either in solution, or in the form of a cream or aerosol, preferably at a pH of about 5.5, in an effective amount and for a time sufficient to effect treatment.

(Abstract.) Also see column 7 lines 11-16:

> I have found that for topical applications of heparin, it is most efficacious to apply the solution in a carrier having an acidic pH and particularly a pH of about 5.5. For reasons that are presently unknown, the medically beneficial uses of heparin are most apparent at acid pH's. Without wishing to be restricted to a particular mode of action of heparin as applicable to the instant invention, it is likely that this pH is favored because heparin interacts with and inactivates molecules involved in an inflammatory reaction, particularly histamine and serotonin and proteolytic enzymes most effectively at acid pH's. Since histamine is known to effect cellular destruction, its inhibition likely facilitates wound healing.

Also column 7 lines 42-44:

> Again, it should be stressed that such compositions preferably have an acidic pH at the site of injury, and particularly a pH of about 5.5.

The Office Action states that "this does not imply that the carrier has to be an at acidic pH to be efficacious or effective, but only to be most efficacious" (Office Action, page 7). However, these

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[3] As noted in references submitted in the prior Response, zinc oxide has a pH of 6.95-7.37.

passages also plainly do not imply that there is *any benefit* to the addition of a basic material such as zinc oxide to heparin – and the proper test for obviousness is whether the prior art teaches some benefit, or provides some other motivation, to combining or modifying the prior art references.[4] Please objectively consider the foregoing passages: can it fairly be said that these would lead an ordinary artisan who is seeking to improve the primary reference (*Saliba*) to use a neutral to basic material (such as zinc oxide) with heparin? We submit that if *Saliba* is fairly and objectively considered, the answer is no.

The Office Action also states at page 7 that "applicant composition is not limited to any particular pH and in fact applicant's claimed carrier (carboxymethlcellulose carrier) should have an acidic pH." But pH is not directly relevant to the independent claims 14, 16, and 18; rather, the pH values of the ingredients used alongside heparin are relevant to whether or not one would truly modify *Saliba*'s heparin compound to include basic ingredients such as zinc oxide. Further, carboxymethlcellulose is *not* in fact acidic – it is *basic*, with pH from 7-10 (see attached references). In fact, *all* of the recited carriers in claims 14, 16, and 18 are similarly substantially neutral to basic in character – which is directly contrary to *Saliba*'s suggestions.

The Office Action also *admits* at the bottom of page 8 of the Office Action that "Saliba suggests... that the heparin solution is most efficacious if an acidic carrier is used", but then states that zinc oxide is not a carrier, and thus will not affect the pH of the solution wherein the heparin is carried. This is false; plainly all ingredients used alongside heparin in the composition are relevant to the *Saliba* pH, including zinc oxide as well as carriers, and thus one of ordinary skill would still find no motivation to add zinc oxide to heparin. Also, setting aside the issue of zinc oxide entirely, note that all of the carriers recited in Applicant's independent claims 14, 16, and 18 are neutral to basic in character – which is directly contrary to the admitted suggestion of *Saliba*, and is thus further basis for unobviousness. Note that *Saliba*, while emphatic that the

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[4] See, e.g., MPEP 2143.01 under heading "THE PRIOR ART MUST SUGGEST THE DESIRABILITY OF THE CLAIMED INVENTION" (and conversely see under the heading "FACT THAT REFERENCES CAN BE COMBINED OR MODIFIED IS NOT SUFFICIENT TO ESTABLISH PRIMA FACIE OBVIOUSNESS").

heparin should be combined with acidic carriers/ingredients, is otherwise quite vague as to the identity of the carriers/ingredients – but it is nevertheless clear that *Saliba*'s acidic carriers/ingredients do not overlap with Applicant's basic carriers/ingredients:

> As alluded to above, a variety of pharmaceutical carriers can be employed with heparin to realize its beneficial uses. Such can be in liquid, solid or vapor form, and can be applied by injection, dripping, spreading or aerosol. A variety of solid pharmaceutical carriers can be imagined including starch, sugars, talc, manitol and the like. Again, it should be stressed that such compositions preferably have an acidic pH at the site of injury, and particularly a pH of about 5.5. It will be understood that the term carrier is meant to include, in addition to the above, buffered and non-buffered liquid.

(*Saliba* at column 7 lines 36-36.) In short, since Applicant's independent claims recite heparin used with zinc oxide and other neutral to basic carriers/ingredients, which is contrary to the admitted suggestion of *Saliba*, the compositions and methods recited in these claims cannot be said to be obvious.

In addition, even if it is assumed for the sake of argument that one *did* regard heparin and zinc oxide as combinable as per *Saliba* and *Costello*, these references also suggest use of a dramatically higher concentration of zinc oxide than the one claimed: *Costello* suggests use of 1.5-4.2 wt% zinc oxide, whereas the claimed invention calls for 1-20 mg/g (i.e., 0.001-0.02 wt%). Thus, even if one combined heparin and zinc oxide as per *Saliba* and *Costello*, the combination would not amount to the one claimed.[5] This is particularly so when it is also considered that the *Saliba*/*Costello* combination would also have dramatically higher heparin than the claimed combination, as discussed above. The Office Action states at page 9 that "the use of different wt% of zinc oxide depends on factors like the severity of the insect bite, the type of

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[5] Please note that it appears this argument was not addressed in the Final Office Action. If the rejection is maintained, please address and respond to these arguments. See MPEP 707.07(f), Answer All Material Traversed ("Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it"); also see Examiner Notes for PTO form paragraphs 7.37 and 7.38 (as reproduced in MPEP 707.07), which require that all relevant arguments by the Applicant be addressed, as well as MPEP 706.07 under "Statement of Grounds" ("the final rejection . . . also should include a rebuttal of any arguments raised in the applicant's reply").

subject treated and the other ingredients that comprises the composition such as heparin," but again this sidesteps the question of whether or not an ordinary artisan would truly find it obvious to construct the claimed composition from the cited references. *Costello* in no way suggests that more (or less) zinc oxide should be used depending on severity of the injury, and more fundamentally, *there is simply nothing that truly suggests that the claimed dramatically lower zinc oxide content should be used.* The sweeping statement that an ordinary artisan would simply choose any percentage of zinc oxide depending on the severity of injury simply does not ring true: how/why does *Costello* truly suggest that a dramatically lower zinc oxide content would be beneficial? Assuming that the Office Action's statement (that one would choose amount in accordance with the severity of injury), wouldn't one of ordinary skill use a *larger* percentage of zinc oxide, as in *Costello*, to account for a wide range of insect bites?

In summary, we submit that if the obviousness inquiry is properly addressed without the use of *per se* reasoning, and if one looks at *Saliba* and asks how an ordinary artisan might *fairly and objectively* be led to improve on *Saliba* in view of *Costello* and the other references of record, one would not arrive at the claimed composition/method. *Saliba* suggests that any ingredient added to a topical heparin composition should be acidic (unlike the claimed zinc oxide and carriers), and even if one did combine heparin and zinc oxide as per *Saliba* and *Costello*, the resulting combination would have vastly greater amounts of both heparin *and* zinc oxide than the combination claimed. Can it fairly be said that one of ordinary skill, after reviewing *Saliba* and *Costello*, would truly combine heparin with non-acidic ingredients (such as zinc oxide) and carriers, and use both heparin and zinc oxide in dramatically lower amounts? If the claimed invention is set out of mind, and *Saliba* and *Costello* are objectively reviewed for all that they suggest, it will be seen that this does not make sense. Rather, it is seen that one would, if anything and at most, use a topical mixture of *Saliba*'s heparin and Costello's aloe vera: aloe is emphasized by *Costello* as being the key ingredient for *Costello*'s cream, and it has an acidic pH.[6]

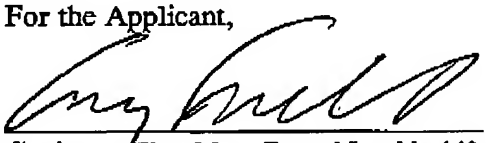
[6] As noted in references submitted in the prior Response, aloe is acidic.

But this is not the claimed invention. We therefore submit that claims 14-17 are novel, unobvious, and allowable in view of the cited references.

3. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

For the Applicant,



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ATTACHMENTS:

- http://www.chemicalland21.com/industrialchem/performancepolymer/CARBOXYMETHYL%20CELLULOSE%20SODIUM%20SALT.htm

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CARBOXYMETHYL CELLULOSE SODIUM SALT

PRODUCT IDENTIFICATION

CAS NO	9004-32-4
SYNONYMS	CM-Cellulose sodium salt; Cellulose glycolic acid, sodium salt; Cellulose sodium glycolate; Cellulose, carboxymethyl ether, sodium salt; Sodium carboxmethylcellulose;
FORMULA	$C_6H_9OCH_2COONa$
MOL WT	
H.S. CODE	3912.31
TOXICITY	Oral rat LD50: > 2000mg/kg
CLASSIFICATION	
DERIVATION	cellulose fiber with sodium hydroxide and chloroacetic acid

PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE	free flowing white to off-white powder
MELTING POINT	
BOILING POINT	
SPECIFIC GRAVITY	1.59
SOLUBILITY IN WATER	soluble
pH	7 - 10 (1% sol.)
VAPOR DENSITY	
AUTOIGNITION	> 300 C
NFPA RATING	Health: 1; Flammability: 3; Reactivity: 0
REFRACTIVE INDEX	
FLASH POINT	
STABILITY	Stable under ordinary conditions

APPLICATIONS

CMC is used primarily in foods, drugs and cosmetics as a viscosifier, emulsion stabilizer, thickener and to improve texture. The main applications of technical grade are in textile warp sizing and paper processing. CMC is also used in detergent as a antiredeposition agent, textile warp-sizing aid, adhesives, latex paints and polishes.

SALES SPECIFICATION

DETERGENT APPLICATION

APPEARANCE	white to off-white powder
VISCOSITY	30cps max (1% sol.)
pH	5 - 9 (1% sol.)
MOISTURE	10.0% max
TRANSPORTATION	
PACKING	
HAZARD CLASS	
UN NO	

OTHER INFORMATION

European Hazard Symbols: n/a; Risk Phrases: ; Safety Phrases: 24/25